INSTRUCTIONS FOR USE

INDICATIONS:
Recommended for balloon atrioseptostomy, an accepted technique in most pediatric cardiology centers for the palliation of several congenital cardiac defects. Balloon atrioseptostomy is performed in conjunction with diagnostic cardiac catheterization and has been carried out after the diagnosis of several congenital cardiac defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

CATHETER DESCRIPTION:
This catheter is a balloon catheter designed for the neonate with congenital heart disease requiring septostomy. It is a dual lumen catheter, 50cm in length. The **611050** has a 9.5mm ± 0.5mm non-compliant balloon, at 1.0cc volume, on the distal end. The **611051** has a 13.5mm ± 0.5mm non-compliant balloon, at 2.0cc volume, on the distal end. The catheter also features an end hole that will accommodate an 0.021" guidewire. The inflated geometry of the balloon is a sphere. There is an imaging band under the balloon for balloon positioning in the left atrium. The catheter tip is angled at 35° to facilitate passage through the interarterial opening in the left atrium. To inflate the balloon of the **9.5mm** catheter to its maximum diameter, 1cc of diluted contrast media is pushed into the balloon extension after purging. To inflate the balloon of the **13.5mm** catheter to its maximum diameter, 2cc of diluted contrast media is pushed into the balloon extension after purging. Catheters are supplied with a one-way stopcock for balloon sealing. The **9.5mm** is primarily for infants less than 2 kg.

HOW SUPPLIED:
Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

WARNING:
- CAUTION: Do not exceed the rated volume of 1cc for the **9.5mm** Catheter. Over inflation may cause balloon rupture.
- CAUTION: Do not exceed the rated volume of 2cc for the **13.5mm** Catheter. Over inflation may cause balloon rupture.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- Use only a 3cc syringe for inflation.
- Use a 3cc syringe for deflation. (For faster deflation, up to a 10cc syringe may be used).
- Do not advance the guidewire, septostomy catheter, or any other component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross contamination.
- The use of excessive force to pull the balloon across the atrial septum must be avoided.

PRECAUTIONS:
- Balloon atrioseptostomy should not be performed for infants older than six weeks. These infants will have thick atrial septums. Reference AHA/ACC guidelines.
- Procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and by aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
- If resistance is felt upon removal, then the balloon, guidewire and the sheath should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
- Before removing the catheter from the sheath it is very important that the balloon is completely deflated.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

POTENTIAL COMPLICATIONS:
Potential complications & adverse effects associated with device use and indication include:
- Infection
- Bleeding
- Inflammation
- Hematoma Formation
- Thromboembolic Events
- Conduction system Injury
- Air embolism
- Death
- Potential balloon separation with subsequent need of snare
- Vascular perforation requiring surgical repair
- Rhythm and conduction disturbances
- Perforation of the left atrial appendage
- Damage to the vascular intima

Any serious incident that has occurred in relation to the device should be reported to BIS and the FDA.

INSPECTION AND PREPARATION:
1. Insert guidewire through the distal tip until guidewire exceeds proximal port.
2. Remove balloon protector. Inspect the catheter for damage prior to insertion.
3. Attach a 3cc syringe half filled with normal saline and attach it to the stopcock, already attached to the balloon port.
4. Purge and flush the catheter through lumen thoroughly, observing for leaks.
5. Point the syringe nozzle downward, aspirate until all air is removed from the balloon, and bubbles no longer appear in the contrast medium.
6. Turn the stopcock off to maintain the vacuum in the balloon.
7. Remove guidewire.

INSERTION Vascular:
1. Prepare a 30% mixture by volume of contrast medium and normal saline.
2. Prepare the subject for the procedure.
3. Catheters may be introduced by percutaneous approach or by transumbilical vein. In the event a percutaneous approach is not feasible, a venous cutdown may be used.
4. The placement of the catheter can be accomplished under fluoroscopic guidance or under special conditions using two-dimensional echocardiographic guidance. Once through the sheath the catheter is passed to the inferior vena cava and into the right atrium. The angled tip facilitates passage across the interarterial opening to the left atrium. In case of difficulty, a 0.021" guidewire is positioned in the left atrium or pulmonary vein. The tip of the catheter has to be free in the left atrium prior to its inflation. The guidewire should be pulled back into the catheter shaft or removed completely before proceeding with septostomy.
5. Balloon septostomy is most safely performed under fluoroscopy or 2-D echo. The balloon must be well identified in the left atrium. The balloon of the **9.5mm** catheter is inflated with 1cc of fluid, the balloon of the **13.5mm** catheter is inflated with 2cc of fluid and the stopcock is closed. CAUTION: Do not exceed the 1cc volume for the **9.5mm** catheter or the 2cc volume for the **13.5mm** catheter. Over-inflation may cause balloon rupture. The balloon is then pulled into the right atrium with a fast, snapping motion. This pulling maneuver must be stopped at the inferior vena cava-right atrial junction and the balloon rapidly readvanced into the right atrium (since balloon is non-compliant, it will not conform to the shape of the IVC and tearing is a possibility). Immediately deflate the balloon by applying negative pressure to the syringe.

   The use of excessive force to pull the balloon across the atrial septum must be avoided. Specifically, the physician should avoid using the entire arm when pulling the balloon across the septum and should instead use only the motion of the wrist. If the balloon does not easily cross the septum using this method, it is recommended that a smaller volume of fluid be used initially. The amount of fluid can then be gradually increased in volume until the desired result is achieved. If the first two steps are not successful, consider static balloon dilation of the atrial septum.

   If necessary, the catheter can be repositioned in the left atrium and the process can be repeated. The number of repeated septostomies performed during one catheterization is determined by the clinical state of the patient and the estimation of effective palliation. This can be done by echocardiography to measure the size of the defect or by inflating the full balloon in the left atrium and bringing it back through the defect to the right atrium without much tension.
6. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal, then the balloon, guidewire, and the sheath should be removed together as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
7. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.
8. Dispose of device after use according to standard hospital protocol for biohazardous devices.

Z-6™ Balloon Sizing Chart

9.5mm

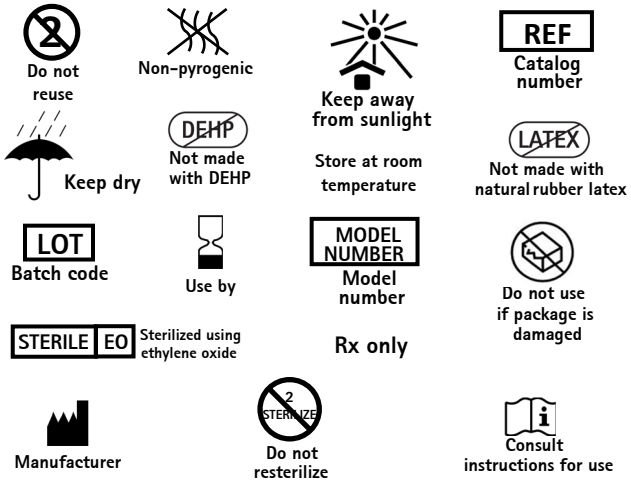
Injected Volume	Average Balloon Diameter
0.7 cc	7.59 mm
0.8 cc	8.25 mm
0.9 cc	8.92 mm
1.0 cc	**9.47 mm**

Caution: Do not exceed the rated volume of ***1.0 cc.*** Over inflation may cause balloon rupture.

13.5mm

Injected Volume	Average Balloon Diameter
1.5 cc	11.69 mm
1.6 cc	12.14 mm
1.7 cc	12.60 mm
1.8 cc	12.99 mm
1.9 cc	13.32 mm
2.0 cc	**13.69 mm**

Caution: Do not exceed the rated volume of ***2.0 cc.*** Over inflation may cause balloon rupture.



WARNING:

These catheters are placed in the extremely hostile environment of the human body. Catheters may fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged before, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters. B. Braun Interventional Systems Inc. cannot warrant or guarantee B. Braun Interventional Systems Inc. accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

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Z-6™ Atrioseptostomy Catheter

Instructions for Use

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CAUTION:
Federal (USA) Law restricts this device to sale by or on the order of a physician.

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